

MEDICATION GUIDE

Ribavirin Capsules USP 200 mg

(rye-bah-VYE-rin)

Read this Medication Guide before you start taking ribavirin, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about ribavirin?

1. **Do Not take ribavirin alone to treat chronic hepatitis C infection.** Ribavirin should be used in combination with **interferon alfa-2b (Intron A)** to treat chronic hepatitis C infection.
2. **Ribavirin may cause a significant drop in your red blood cell count and cause anemia in some cases. Anemia has been associated with worsening of Heart Problems and in rare cases can cause a Heart Attack and Death.** Tell your healthcare provider if you have ever had any heart problems. Ribavirin may not be right for you. **Seek medical attention right away if you experience chest pain.**
3. **Ribavirin may cause Birth Defects or the Death of your unborn baby. Do Not Take Ribavirin if you or your sexual partner is pregnant, or plan to become pregnant. Do Not become Pregnant within 6 months after discontinuing ribavirin therapy.** You must use 2 forms of birth control when you take ribavirin and for the 6 months after treatment.

Females must have a pregnancy test before starting ribavirin, every month while taking ribavirin, and every month for the 6 months after the last dose of ribavirin.

If you or your female sexual partner becomes pregnant while taking ribavirin or within 6 months after you stop taking ribavirin, tell your healthcare provider right away. You or your healthcare provider should contact the ribavirin pregnancy registry by calling 1-800-593-2214. The ribavirin pregnancy registry collects information about what happens to mothers and their babies if the mother takes ribavirin while she is pregnant.

What is ribavirin?

Ribavirin is a medicine used with interferon alfa-2b (Intron A) to treat chronic (lasting a long time) hepatitis C infection in people 3 years and older with liver disease.

It is not known if ribavirin use for longer than one year is safe and will work.

It is not known if ribavirin use in children younger than 3 years old is safe and will work.

Who should not take ribavirin?

See “What is the most important information I should know about ribavirin?”

Do not take ribavirin if you have:

- or ever had serious allergic reactions to the ingredients in ribavirin

capsules. See the end of this Medication Guide for a complete list of ingredients.

- certain types of hepatitis (autoimmune hepatitis).
- certain blood disorders (hemoglobinopathies).
- severe kidney disease.
- taken or currently take didanosine (VIDEX®).

Talk to your healthcare provider before taking ribavirin if you have any of these conditions.

What should I tell my healthcare provider before taking ribavirin?

Before you take ribavirin, tell your healthcare provider if you have or ever had:

- treatment for hepatitis C that did not work for you.
- breathing problems. ribavirin may cause or worsen breathing problems you already have.
- vision problems. Ribavirin may cause eye problems or worsen eye problems you already have. You should have an eye exam before you start treatment with ribavirin.
- certain blood disorders such as anemia (low red blood cell count).
- high blood pressure, heart problems, or have had a heart attack. Your healthcare provider should check your blood and heart before you start treatment with ribavirin.
- thyroid problems
- liver problems other than hepatitis C infection
- human immunodeficiency virus (HIV) or any immunity problems
- mental health problems, including depression or thoughts of suicide
- kidney problems
- an organ transplant
- diabetes. Ribavirin may make your diabetes worse or harder to treat.
- any other medical condition
- are breastfeeding. It is not known if ribavirin passes into your breast milk. You and your healthcare provider should decide if you will take ribavirin or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Ribavirin may affect the way other medicines work.

Especially tell your healthcare provider if you take didanosine (VIDEX®) or azathioprine (Imuran® and Azasan®).

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take ribavirin?

- Take ribavirin exactly as your healthcare provider tells you. Your healthcare provider will tell you how much ribavirin to take and when to take it.
- Take ribavirin with food.
- Take **ribavirin capsules** whole. Do not open, break, or crush **ribavirin capsules** before swallowing. If you cannot swallow **ribavirin capsules** whole, tell your healthcare provider.
- If you miss a dose of ribavirin, take the missed dose as soon as possible during the same day. Do not double the next dose. If you have questions

about what to do, call your healthcare provider.

- If you take too much ribavirin, call your healthcare provider or Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of ribavirin?

Ribavirin may cause serious side effects, including: See “What is the most important information I should know about ribavirin?”

- **Swelling and irritation of your pancreas (pancreatitis).** You may have stomach pain, nausea, vomiting, or diarrhea.
- **Serious breathing problems.** Difficulty breathing may be a sign of a serious lung infection (pneumonia) that can lead to death.
- **Serious eye problems** that may lead to vision loss or blindness.
- **Dental problems.** Your mouth may be very dry, which can lead to problems with your teeth and gums.
- **Severe depression**
- **Suicidal thoughts and attempts.** Adults and children who take ribavirin, especially teenagers are more likely to have suicidal thoughts or attempt to hurt themselves while taking ribavirin. Call your healthcare provider right away or go to the nearest hospital emergency room if you have new or worse depression or thoughts about suicide or dying.
- **Severe blood disorders.** An increased risk when used in combination with azathioprine
- **Growth problems in children.** Weight loss and slowed growth are common in children during combination treatment with INTRON A. Most children will go through a growth spurt and gain weight after treatment stops. Some children may not reach the height that they were expected to have before treatment. Talk to your healthcare provider if you are concerned about your child’s growth during treatment with ribavirin and INTRON A.

Tell your healthcare provider right away if you have any side effect that bothers you or that does not go away.

The most common side effects of ribavirin include:

- flu-like symptoms - feeling tired, headache, shaking along with high temperature (fever), nausea, and muscle aches.
- mood changes, feeling irritable.

The most common side effects of ribavirin in children include:

- a decrease in the blood cells that fight infection (neutropenia).
- a decrease in appetite.
- stomach pain and vomiting.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ribavirin. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ribavirin?

- Store **ribavirin capsules** between 59°F to 86°F (15°C to 30°C).

Keep ribavirin and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF RIBAVIRIN.

It is not known if treatment with ribavirin will cure hepatitis C virus infections or prevent cirrhosis, liver failure, or liver cancer that can be caused by hepatitis C virus infections. It is not known if taking ribavirin will prevent you from infecting another person with the hepatitis C virus.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ribavirin for a condition for which it was not prescribed. Do not give ribavirin to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ribavirin. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or health care provider for information about ribavirin that is written for health professionals.

What are the ingredients in ribavirin capsules USP?

Active ingredient: ribavirin

Inactive ingredients: corn starch, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, and povidone. The capsule shell consists of gelatin and titanium dioxide. The capsule is printed with edible blue pharmaceutical ink which is made of FD&C Blue #2 aluminum lake, propylene glycol, shellac and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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